

Chapter One

Purpose and Need for Action

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1.1 Introduction

1.1.1 The Emerging Need to Define the Role, If Any, of the National Park Service When Research Involving Study of NPS Specimens Discovers Commercially Valuable Results

The outcome of this draft EIS (DEIS) is the clarification of the rights and responsibilities of researchers and National Park Service (NPS) managers in connection with the use of valuable discoveries, inventions, and other developments resulting from research involving research specimens lawfully collected from national parks.¹ The commercial use or sale of research specimens themselves is prohibited by regulation (*see* 36 CFR 2.1). However, the commercial use of knowledge derived from specimens via research is not prohibited. Commercial use of research results has, in the past, been left entirely up to researchers without involvement from the NPS.

In Chapter 2 of this DEIS, the NPS proposes new management practices that would require researchers and their institutions to enter into benefits-sharing agreements with the NPS in the event that they wish to commercialize their research results. The NPS is using the analyses presented in this DEIS to evaluate the proposed implementation of benefits-sharing as well as reasonable alternatives to it. This DEIS reveals the possible environmental impacts of choosing whether or not to implement a certain type of contract; hence, the nature of this DEIS is such that its affected environment and impact topics relate primarily to administrative functions of the NPS.

What are research specimens?

“Research specimens” are those items an authorized researcher has permission to collect from an NPS unit pursuant to an NPS Scientific Research and Collecting Permit (“NPS research permit”) issued by the NPS in accordance with 36 CFR 2.5.

What are research results?

For purposes of this DEIS, “research results” are the data, discoveries, inventions, or other knowledge resulting from “research activities.”

What are research activities?

“Research activities” are the actions taken by researchers or their sponsoring organizations or companies in accordance with an NPS research permit, including research specimen collections and analysis conducted for scientific purposes.

The important distinction between research specimens (“natural products”) and research results is intended to prevent the marketing or other commoditization of NPS resources, while not interfering with the legitimate development of useful and therefore valuable discoveries from research involving NPS research specimens. For example, NPS regulations and policy provide that specimens collected from a national park area cannot be used as raw material in the manufacture of commercial products.² In a specific example, ginseng collected under a research permit could not then be used to make a product that is sold commercially that contains the ginseng. However, there is no prohibition against the commercial use of synthetic or other non-naturally occurring compounds whose discovery and development resulted from research that initially involved the biological material collected (ginseng in this example) from a national park pursuant to an NPS research permit.

This DEIS addresses the development of servicewide management practices relating to the implementation of existing NPS policy. A National Environmental Policy Act (NEPA) document of this sort has a broad scope, is general in nature, and is termed a “programmatic EIS.” It describes the conditions under which certain activities may be authorized and provides potential general standards for management. This EIS evaluates alternative choices for implementing existing policies while evaluating the possible environmental impacts of activities that may be included in any proposal.

Because the description of the potential program at this level is general, the analysis of environmental impacts is conducted at a general level. Thus, the type and amount of data relating to possible impacts is presented at the general level, and does not include site-specific details. If Alternative B (Implement Benefits-Sharing) is selected, then NEPA review (EIS, EA, or CE) of specific benefits-sharing agreements that might be established by individual parks in the future can be tiered from this programmatic EIS. If an individual park proposed site-specific resource management projects using non-monetary or monetary benefits generated by a benefits-sharing program, such projects would receive a separate environmental review for potential project-specific impacts in compliance with NEPA.

1.2 Background

1.2.1 Changing Technologies and Their Role in the Programmatic Benefits-Sharing Proposal

The NPS has determined that it needs to propose servicewide NPS management practices to address the NPS’s interest in the use of the results of research involving NPS research specimens. Although the NPS has concluded that research permit regulations are “adequate to ensure protection of park resources” during the conduct of research activities,³ and some benefits resulting from research are shared with the NPS,⁴ regulations and policies stop short of providing for routine benefits-sharing related to commercially valuable research results.

Currently, an average of more than 200 national parks annually host independent research efforts, authorized under permits generated under current policies and procedures. As discussed below (Section 1.3), the current permit policy focuses on potential impacts of proposed research activities on parks and does not fully address the interests of the NPS in the potential results of such research. Current NPS policy regarding permits controls access to park resources, but the policy does not always take full advantage of opportunities to coordinate research activities between independent scientists and park managers, nor does it guarantee that the NPS will eventually share in the benefits from independently conducted research.

The proposal to implement benefits-sharing (Alternative B) would provide for the efficient and equitable sharing of valuable research results generated by research involving NPS research specimens (*see* Chapter 2, Alternative B). New and changing technologies have made this proposal desirable, as the following recent events illustrate:

(1) New research techniques, particularly in microbiology and molecular biology, have allowed remarkable advances in technologies with industrial, medical, and other marketable

What is the NPS benefits-sharing proposal?

The management practices proposed in Alternative B (Implement Benefits-Sharing) would apply to research projects involving research specimens collected from units of the National Park System that subsequently resulted in useful discoveries or inventions with some valuable commercial application. A benefits-sharing agreement would provide the terms and conditions for the further development and use of such valuable discoveries, inventions, or other research results. All such researchers would be required to enter into a benefits-sharing agreement with the NPS before using their research results for any commercial purpose. See Chapter 2, Section 2.4 for a description of the “benefits” that could be generated by benefits-sharing agreements. Under the proposal (Alternative B), a benefits-sharing agreement would not regulate or authorize any researcher’s access to NPS resources.

uses. Studies of park resources, including rare bacteria and unique plants and animals, expand beneficial scientific knowledge, and research results occasionally generate substantial commercial profits.⁵ This DEIS uses the term “bioprospecting” to describe biological research that could result in a discovery with some commercial application (*see* Chapter 3, Section 3.4.3). Bioprospectors (researchers who engage in bioprospecting) are the researchers most likely to be involved in benefits-sharing. Bioprospecting does not require the sort of grand-scale resource consumption required by the kinds of extractive industries that are typically associated with the term “prospecting,” such as timber harvesting and mining. In this case, the “prospecting” is for new knowledge.

(2) In recent years, the value of research results has been enhanced by developments in intellectual property rights laws, evolving trade practices, and advances in specimen collection and product-development research. Some research discoveries, including those derived from study of NPS research specimens, are potentially worth millions of dollars to private firms (*see also* this chapter, Section 1.7.1). Until now, the NPS has had no provisions to allow the NPS to claim any share of these economic benefits, which often don’t materialize until years or even decades after completion of the permitted research.

(3) Yellowstone National Park has taken the lead in clarifying issues and options related to the current NPS policy for the eventual sharing of benefits between private individuals, companies, and the NPS. In September 1995, Yellowstone convened a major multidisciplinary conference on microbiological research in extreme environments such as the park’s hot springs. The conference included discussions with the university and corporate scientific research communities, conservationists, park managers, legal experts, journalists, and others to explore issues and possible options for NPS management of valuable research results.

(4) At the request of the NPS director in 1996, Yellowstone National Park negotiated a landmark draft agreement with the Diversa Corporation of San Diego, California. The agreement (finalized in May 1998 after extensive public comments) provided for the NPS to share in the economic and scientific research benefits from Diversa research involving specimens collected at Yellowstone.⁶

(5) Early in 1998, the Yellowstone–Diversa agreement was challenged in court on several grounds related to the NPS Organic Act and other federal laws. The court upheld the Yellowstone–Diversa agreement and dismissed the plaintiffs’ case with prejudice, but required the NPS to complete a NEPA analysis of the agreement (*see* this chapter, Section 1.7.6).

This DEIS provides a programmatic NEPA analysis for benefits-sharing agreements servicewide. In addition, this DEIS analyzes the potential impact of benefits-sharing in an individual park context, including Yellowstone National Park, which will comply with the court’s mandate to evaluate the impacts of the benefits-sharing agreement between Yellowstone National Park and Diversa Corporation: the Yellowstone–Diversa Cooperative Research and Development Agreement (CRADA).

This DEIS examines the potential environmental impacts of three alternatives: implementing benefits-sharing agreements when information derived from research specimens collected from units of the National Park System results in commercial value; continuing the current practice of not requiring benefits-sharing (the “no action” alternative); and barring researchers whose studies might result in commercially viable products from collecting research specimens in the national parks.

1.2.2 The National Park System’s Natural Resources Invite Scientific Studies

Bioprospectors often focus their searches in the world’s unique and pristine ecosystems, and national parks have been popular bioprospecting sites for many years. At nearly 400 park units and 84.4 million total acres, the National Park System constitutes a vast and complex diversity of ecosystems that represent a large majority of the variety of physical and biological features found within the U.S. today.⁷ Parks attract independent researchers in part because parks offer opportunities to study preserved and protected natural resources.

The fundamental purpose of the national park system, established by the NPS Organic Act and reaffirmed by the General Authorities Act, as amended, begins with a mandate to conserve park resources and values.⁸ This has resulted in a National Park System containing well-preserved examples of North America’s biological diversity.

To a large extent, the biodiversity of the U.S. is exemplified by the National Park System.⁹ Scientists recognize a variety of “ecoregion divisions” in the U.S., based upon each division’s unique combination of climate, landforms, vegetation, soil composition, fauna, and other factors.¹⁰ National park units are located within every terrestrial ecoregion division of the U.S., so the NPS conserves and manages examples of nearly all the variety of life found in the United States today (*see* figures 1.2.2-1 and 1.2.2-2 and table 1.2.2).

The natural resources managed by the NPS are attractive to researchers precisely because of the protection they have been afforded within the parks. For example, some organisms that are no longer commonplace in the U.S. can still be found within national parks because they are legally protected land- or waterscapes, and parks are often more pristine than the lands that surround them.

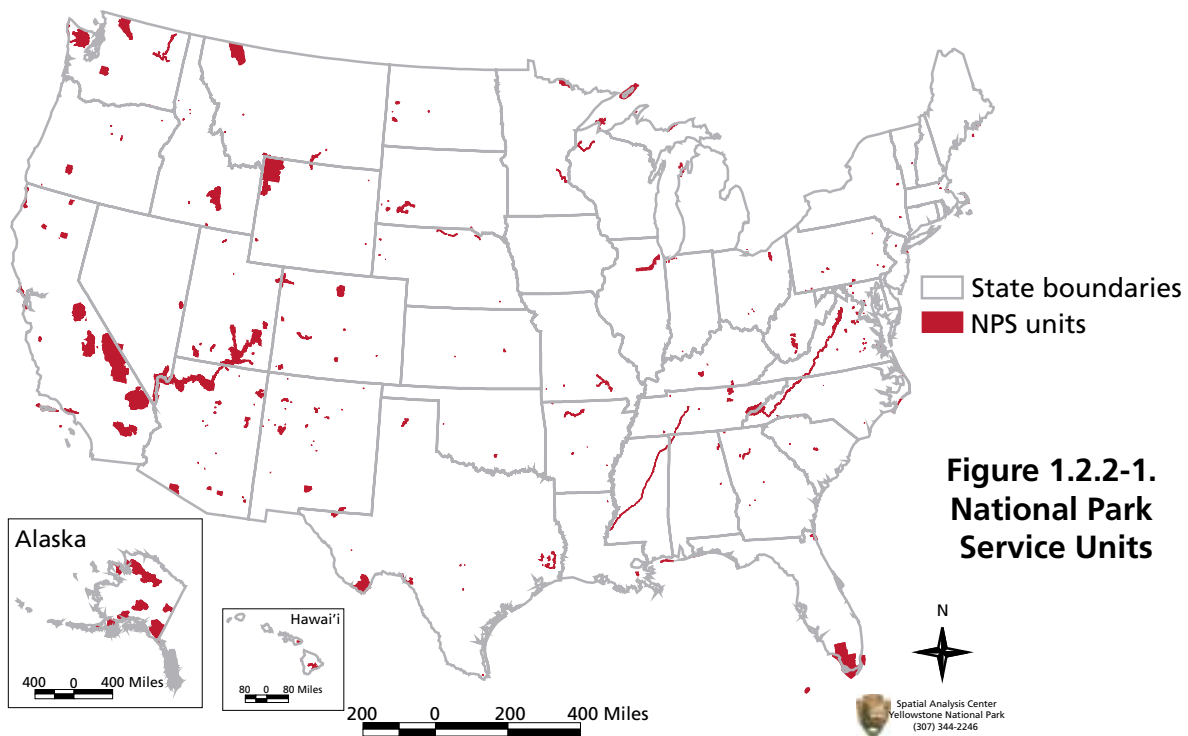


Figure 1.2.2-1. National park units are spread across the United States.

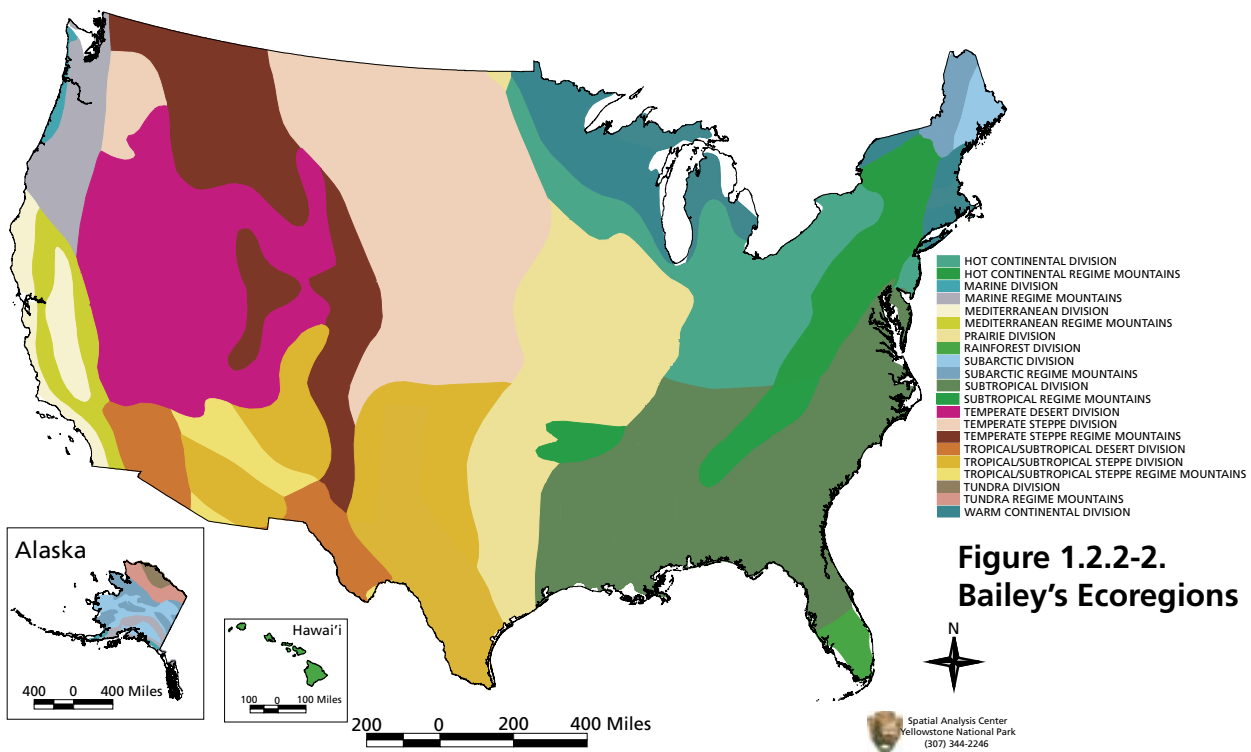


Figure 1.2.2-2. National park units are located within every terrestrial ecoregion of the U.S.

National parks offer unique opportunities to study natural systems and living things. It is increasingly obvious to park managers, scientists, and others that the more that is learned about the organisms existing in parks, the more it is confirmed that national parks are important places of special and complex biological diversity. Because of this special status, the NPS expects that researchers will continue to seek out opportunities to study natural resources in the national parks.

Table 1.2.2. National Park System acreage in each ecoregion division

Ecoregion division	Park units	NPS acres
Hot Continental	70	797,240
Hot Continental Regime Mountains	18	792,250
Marine	4	19,940
Marine Regime Mountains	11	10,134,550
Mediterranean	14	650,480
Mediterranean Regime Mountains	11	2,048,900
Prairie	9	58,570
Rainforest Regime Mountains	6	259,110
Savanna	4	2,512,620
Savanna Regime Mountains	5	16,490
Subarctic	4	3,116,240
Subarctic Regime Mountains	4	18,651,840
Subtropical	66	630,730
Subtropical Regime Mountains	1	5,730
Temperate Desert	18	1,659,760
Temperate Desert Regime Mountains	5	351,410
Temperate Steppe	20	440,930
Temperate Steppe Regime Mountains	23	4,356,930
Tropical/Subtropical Desert	20	7,951,130
Tropical/Subtropical Regime Mountains	11	216,920
Tropical/Subtropical Steppe	33	3,066,250
Tundra	7	3,581,970
Tundra Regime Mountains	7	20,631,280
Warm Continental	12	679,560
Warm Continental Regime Mountains	2	780

Table 1.2.2. National parks are represented in every ecoregion division in the United States.

1.2.3 Current Research in U.S. National Parks

The NPS has authorized the collection of research specimens from units of the National Park System for qualified research purposes as an established national park management activity for more than 100 years. This long-standing practice today is administered through Scientific Research and Collecting Permits (“research permits”) issued and administered by the NPS under 36 CFR 1.6 and 2.5. Every research permit application is reviewed for compliance with NEPA requirements and other laws, regulations, and policies.¹¹ Park superintendents are required to “include in a permit the terms and conditions that the superintendent deems necessary to protect park resources.”¹²

A thorough understanding of natural resources is essential to the effective management and long-term preservation of national parks, and requires a sound scientific basis.¹³ The NPS

is increasingly enlisting the skills and talents of research partners to develop the scientific information needed to make effective management decisions, and is striving to make the parks more accessible to scientists (*see also* Chapter 3, Section 3.2).

National parks offer unique opportunities to study natural systems and living things, and the NPS encourages independent researchers to study park resources. Scientific research is encouraged by the NPS, provided that research activities cause no harm to the parks. Research activities may be conducted by any scientist who qualifies for an NPS Scientific Research and Collecting Permit (research permit) without regard to whether that scientist is affiliated with or funded by public or private sources.¹⁴ All researchers who obtain NPS research permits, whether from public or private entities, are subject to the same NPS scientific research and specimen collection laws, regulations, policies, and guidelines. Although researchers may apply for permission to conduct research that may include collecting research specimens in any of the nearly 400 park units of the NPS, the nearly 300 parks that have already hosted independent research are most likely to do so in the future.¹⁵

As part of the research permit terms, scientists are required to submit a yearly summary of their park research activities, known as an Investigator's Annual Report (IAR). In addition, copies of field notes and scientific publications may be required by the park. From 1992 through 2004, the NPS received approximately 30,000 IAR reports about permitted scientific studies occurring in national parks (*see also* Chapter 3, Section 3.4.1).¹⁶ Between 1992 and 2004, 289 different park units received IAR reports (*see figure 1.2.3*).¹⁷ The number of parks

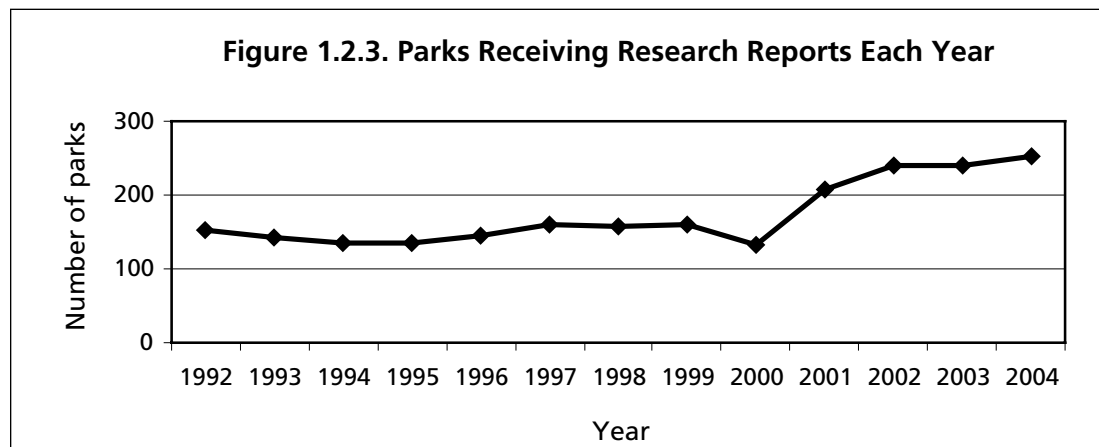


Figure 1.2.3. An average of 235 parks received research reports (IARs) each year during 2001–2004.

receiving IARs has been significantly larger in recent years (2001–2004, when an average of 235 parks received IARs each year), than it was in the past (1992–1999).

In order to make well-informed management decisions, NPS resource managers follow leads found in IARs, and use the results and conclusions presented in research publications. The NPS natural resources bibliography database contains approximately 246,000 entries, including more than 70,000 research articles published in scientific journals and approximately 107,000 formal and informal scientific reports about park natural resources.¹⁸

1.2.4 Commercial Applications of NPS-related Research

Advances in research technologies, intellectual property rights laws, and other fields now make it possible to generate substantial scientific and economic benefits from research activities in ways that were not possible—or even conceived of—in the past. Some research results involving study of specimens collected in U.S. national parks have provided useful and valuable commercial applications. In some cases, such research results have been patented. Research with potential for commercial application continues to occur under the authority of NPS research permits.

1.2.4.1 NPS-related research results protected by patents

Between 1978 and 2003, the U.S. Patent Office issued at least 45 patents that involved research results related to the study of biological material originating in U.S. national parks (see figure 1.2.4.1). Forty-three of these patents related to inventions involving research specimens first collected at Yellowstone National Park. Two involved research specimens collected at Yosemite National Park. The patents described a wide variety of inventions.

The first reported potential commercial application of research results based on the study of NPS research specimens was brought to the agency's attention in 1980, when it was discovered that the Department of Energy had filed a patent application on a high-temperature fermentation process derived from results of research on a microorganism collected at Yellowstone National Park.

Media reports about research results involving research specimens collected in national parks

In 1993, it was reported that research projects involving seven different types of thermophilic microorganisms originally collected at Yellowstone National Park had resulted in the following discoveries with actual or potential commercial applications: oxidizing sulfide; turning cornstarch into a road de-icer; making enzymes used in molecular biology; making enzymes used in studying DNA; producing enzymes used to make perfumes and lactic acid; and converting cellulose into ethanol.¹⁹

In March 1994, it was reported that “[s]ome discoveries with commercial application include microbes that ferment cellulose from corn cobs into ethanol (*Thermoanaerobacter ethanolicus*); turn corn starch into a natural road de-icer (*Clostridium thermoautotrophicum*); produce enzymes used to make perfume and lactic acid (*Thermoanaerobium brockii*); and convert corn starch to sugar (*Acidothrmus cellulolyticus*).”²⁰

Later in 1994, there were reports that research on several strains of previously unknown types of microorganisms first discovered at Carlsbad Caverns National Park produced substances that could inhibit or kill leukemia cells.²¹

In 1996, it was reported that research carried out at the Department of Energy's Pacific Northwest Laboratory involving samples of *Sulfolobus acidocaldarius* originating at Yellowstone National Park had resulted in the discovery and development of new processes for recycling discarded rubber tires.²²

Likewise, in 1997, it was reported that a variety of different research projects involving thermophilic microorganisms originating from Yellowstone National Park resulted in the following discoveries with potential commercial applications: improving texture of baked goods; converting milk to cheese; tenderizing meat; improving clarity, flavor, and foam in beer brewing; removing oils and grease from fabrics; breaking down wood components in paper production; replacing chemicals in paper bleaching; improving textiles' ability to absorb dyes; and replacing chemicals in tanning leather.²³

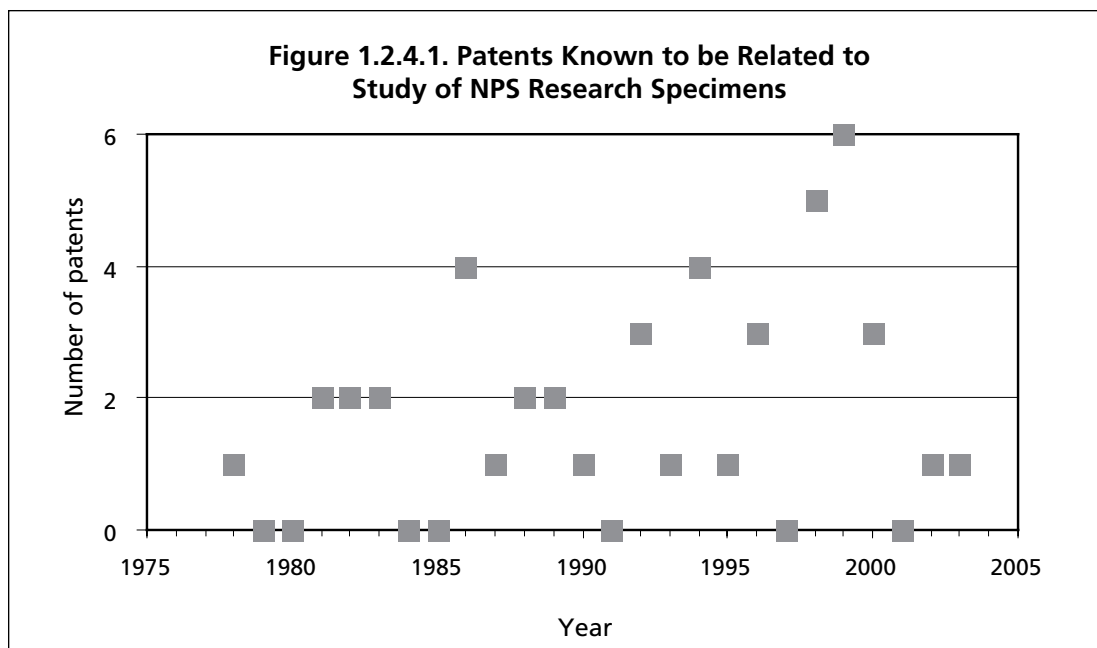


Figure 1.2.4.1. Between 1978 and 2003, The U.S. Patent and Trademark Office granted at least 45 patents based upon research results related to the study of biological material originating in U.S. national parks.

The best-known example of valuable research results involving study of an NPS research specimen was the invention of the Polymerase Chain Reaction (PCR), a process that facilitates widespread uses of DNA analyses and revolutionized the study of biology. PCR generated significant profits for its owners. The PCR patents disclosed that the process used “Taq polymerase,” an enzyme isolated from *Thermus aquaticus* bacteria collected in Yellowstone National Park and then grown in the laboratory for further study. The importance of research involving *T. aquaticus* was summarized in Congressional testimony offered by D. Allan Bromley (then Director of the White House Office of Science and Technology Policy and Science Advisor to President George H. W. Bush) in 1991:

*Thomas Brock, a microbiologist at the University of Wisconsin [sic], discovered a form of bacteria in the thermal vents of Yellowstone that can survive at very high temperature. From these bacteria an enzyme was extracted that is stable at near-boiling temperatures. Nearly two decades later this enzyme proved to be vital in the process known as the polymerase chain reaction, which is used to duplicate specific pieces of DNA. Today, PCR is the basis of a multimillion dollar business with applications ranging from the rapid diagnosis of disease to forensic medicine.*²⁴

Other patents related to park-related research results include but are not limited to the following commercial purposes:

- Enzymes that can be utilized in a wide variety of industries including food processing, baking, pharmaceuticals, agriculture, textiles, detergents, and cosmetics;

- Biologically based methods and products used for bioremediation of hazardous waste;
- Methods and products to enhance oil recovery and remove sulfur compounds and metals from the crude oil;
- New compounds with anti-tumor and antibiotic activity; and
- A nanotechnology method for building extremely small structures for purposes such as high-speed computers.

The only available information about the commercial value of patents related to the study of NPS specimens concerns the patents related to the development of PCR. The economic value associated only with the acquisition of the patent rights resulting from the invention of PCR has been reported to be in excess of \$300 million. The economic value of the subsequent development and use of those patents has been reported to be as much as \$100 million annually.

Not all patented inventions generate revenue or other income. There are no published statistical reports that document the “value” of individual patents, and the NPS has neither required any reports nor systematically collected information concerning revenue or other income generated by research results involving study of research specimens originating from U.S. national parks.

Patent applications related to the study of NPS specimens continue to be filed. For example, at least three NPS-related patent applications were filed in 2002, and at least six in 2003.

1.2.4.2 Commercial uses of research results without patenting

Research results can be used for commercial application without being patented. For example, the Diversa Corporation announced in early 2002 that it was beginning to market a new product identified as Pyrolase 200™, which resulted from research involving thermophilic microorganisms collected at Yellowstone National Park. Pyrolase 200™ is not the subject of a patent.

Researchers can also derive income from the development of a service for hire. For example, a researcher’s major source of income could be derived from performing research for others, under contract, using proprietary methods the researcher developed from study of NPS research specimens.

1.3 Need for a Proposal to Implement Benefits-Sharing

(Specific Problems with Existing Procedures)

The National Park Service has determined that it needs servicewide guidance to address the NPS’s interest in the financial and other benefits from the results of research involving park research specimens. Alternative B’s proposal to implement benefits-sharing responds to the new understanding of the potential for commercial application of research results described in Section 1.2.4 of this chapter.

The preparation of this DEIS will ensure that the basic foundation for decision-making regarding benefits-sharing has been developed in consultation with interested stakeholders and other members of the public, and adopted by park managers and NPS leadership after an adequate analysis of the potential environmental impacts of alternative courses of action. In addition, it will fulfill requirements ordered by the federal district court for the NPS to complete any and all review mandated by NEPA in regard to benefits-sharing in the NPS.

The need to propose new NPS management practices for benefits-sharing is indicated by the difference between the conditions that presently exist and the desired future conditions that could be met by the objectives discussed in Section 1.4 of this chapter. The following unresolved issues and concerns contrast with the objectives outlined below and include elements included in Alternative B's programmatic proposal to implement benefits-sharing.

1.3.1 Existing Conditions: Clarity of Rights and Responsibilities Regarding Research Results

The rights and responsibilities of researchers and NPS managers in connection with the allocation of benefits from valuable discoveries, inventions, and other developments resulting from research involving research specimens lawfully collected from national parks are unclear. Section 5935(d) of the National Parks Omnibus Management Act of 1998 (NPOMA) states, "The Secretary [of the Interior] may enter into negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements." Detailed NPS guidance on how to accomplish this does not exist.

NPS research permits require benefits-sharing in concept, but provide no details on how to achieve that sharing. All NPS research permits are issued subject to the condition that research results may not be used for commercial purposes unless the researcher has entered into a benefits-sharing agreement with the NPS.²⁵ However, the NPS has no standardized, servicewide benefits-sharing agreements in use and provides no guidance to parks regarding the elements necessary to include in a benefits-sharing agreement. The absence of such systematic guidance has resulted in confusion among some members of the public and research community, as well as within some parts of the NPS.

NPS policies do not adequately describe the critical difference between commercial use of research specimens and commercial use of research results.²⁶ Commercial use of research specimens is prohibited (*see* 36 CFR 2.1). However, the commercial use of knowledge derived from the specimens via research (research results) is not prohibited. Commercial use of research results has, in the past, been left entirely up to researchers, without involvement from the NPS. The lack of clarity about the meaning of "commercial or other revenue-generating purposes" has resulted in confusion among some members of the public and the research community, as well as within some parts of the NPS.

The NPS's standardized research permits state that "unauthorized transfers [of collected research specimens] to third parties is prohibited."²⁷ This provision enables the NPS to monitor the disposition of specimens. However, the servicewide standardized procedures to authorize such transfers apply only to permanently retained specimens and do not provide guidance about transfers of specimens that are intended to be consumed in analysis. The

absence of such systematic guidance for non-permanent specimens has resulted in confusion among some members of the public and research community, as well as within some parts of the NPS regarding when specimen transfer authorizations must be requested and how to act upon such requests.

1.3.2 Existing Conditions: Science for Park Management

The National Parks Omnibus Management Act of 1998 (NPOMA) directs the NPS to take necessary measures “to assure the full and proper utilization of the results of scientific study for park management decisions” while encouraging use of national parks by researchers “for study to the benefit of park management as well as broader scientific value.” The NPS has not implemented benefits-sharing although clear legal authority exists to do so. Therefore, the NPS is not using every means at its disposal to assure full utilization of scientific study for park management. The need for more and better scientific information about park plants, animals, ecosystems, and their interrelationships is widely recognized.²⁸ Some collaboration currently occurs between the NPS and researchers, but it is often sporadic and inconsistent, because the NPS sometimes fails to use existing requirements or incentives for researchers to engage in closer partnerships with parks. In many cases, scientists conducting research involving park resources have more knowledge about those resources than NPS staff (*see* Chapter 3, Section 3.2.1). Park managers often find themselves making unnecessarily difficult decisions because they have not adequately obtained the scientific information that exists.

In order to further resource protection goals, park management strives to inform and educate the public about park resources through interpretation of available scientific knowledge. A fundamental goal of NPS interpretation is to present accurate information in such a way that people will begin to understand and appreciate the significance of the parks and their resources.²⁹ The quality of information used for interpretive services is dependent on the quality of the available scientific information about park resources (*see* Chapter 3, Section 3.3.4).

1.4 Objectives of the Proposal and Its Alternatives (*The Purpose of the EIS*)

The following objectives were identified to help determine the reasonableness of each alternative, and to select the preferred alternative and the environmentally preferred alternative (the ultimate selection of the environmentally preferred alternative is guided by the impact analysis in Chapter 4). These objectives proceed from NPS mandates that include legislation, regulations, executive orders, and governing policies. The objectives were identified based on the existing conditions described in Section 1.3 of this chapter.

The alternatives together examine a range of possible solutions to the problems discussed in the existing conditions while addressing the objectives of this DEIS. Meeting the objectives will advance the NPS from existing conditions toward desired future conditions.

1.4.1 Clarity of Rights and Responsibilities Regarding Research Results

The rights and responsibilities of researchers and NPS managers in connection with research results involving study of NPS research specimens will be clarified by selection of one of the alternatives in this DEIS.

OBJECTIVE 1: Identify the role, if any, of the NPS in the event a researcher wishes to commercialize his/her research results involving study of NPS research specimens.

Objective 1.1: Determine whether or not benefits-sharing will be required.

Objective 1.2: Ensure equity and efficiency in connection with any benefits-sharing agreements between the NPS and independent researchers.

Alternative B (Implement Benefits-Sharing) must provide enough information about proposed agreements to allow all parties to anticipate that such agreements would likely be equitable and efficient.

Objective 1

Identify the role, if any, of the NPS in the event a researcher wishes to commercialize his/her research results involving study of NPS research specimens.

Objective 1.1: Determine whether or not benefits-sharing will be required.

Objective 1.2: Ensure equity and efficiency in connection with any benefits-sharing agreements between the NPS and independent researchers.

1.4.2 Science for Park Management

The National Parks Omnibus Management Act of 1998 (NPOMA) directs the NPS “to assure that management of units of the National Park System is enhanced by the availability and utilization of a broad program of the highest quality science and information.”³⁰

OBJECTIVE 2: Strengthen conservation and protection of resources managed by the NPS by deepening understanding of biodiversity and physical and biological processes.

Objective 2.1: Enhance the scope and quality of scientific data reported to the NPS by the research community.

A thorough understanding of resources is essential to the effective management and long-term preservation of national parks, and requires a sound scientific basis.³¹ Virtually all parks have challenges to their conservation mandate that only good science—meaning new knowledge—can define with sufficient detail to allow park managers to meet those challenges. Knowledge from researchers who could enter into benefits-sharing agreements could provide park managers with new, high-quality sources of knowledge to manage park

resources that would be otherwise unavailable to them.

Objective 2.2: Strengthen the scientific capacity of NPS managers through increased collaboration with independent researchers.

“Scientific capacity” is used here to mean the ability to perform scientific activities such as collecting and analyzing data and applying the results to management decision-making. Although the NPS performs a wide range of mission-oriented science in support of its natural and cultural resource stewardship responsibilities, it employs few research-grade scientists. The cooperative involvement of research experts outside the NPS (federal and non-federal public and private agencies, organizations, individuals, and other entities) regularly assists the NPS with obtaining information essential for effective resource management.³²

Objective 2

Strengthen conservation and protection of resources managed by the NPS by deepening understanding of biodiversity and physical and biological processes.

Objective 2.1: Enhance the scope and quality of scientific data reported to the NPS by the research community.

Objective 2.2: Strengthen the scientific capacity of NPS managers through increased collaboration with independent researchers.

1.4.3 Research Permit Issuance Is Not Influenced By Potential Benefits-Sharing

In the absence of any mitigation measures, implementation of Alternative B (Implement Benefits-Sharing) could result in inappropriate consideration of separate benefits-sharing issues at the time NPS research permits are issued. For example, some park officials might be inclined to approve a permit based on the applicant’s representation that valuable research results were likely, whereas other park officials might be inclined to disapprove permit applications involving commercial research firms for reasons not related to the merits of the proposed research activity.

In addition, because the thorough understanding of resources essential to effective management of national parks requires a sound scientific basis, no alternative should discourage researchers from conducting park-related research.

OBJECTIVE 3: Ensure that the NPS research permitting process is independent, objective, and unaffected by actions proposed in this DEIS.

Objective 3.1: Research involving units of the NPS continues to be permitted in accordance with all laws and is unaffected by alternatives proposed in this DEIS.

No alternative would change the regulations and practices that mitigate against improper issuance of NPS research permits. Every research proposal is reviewed for compliance with

NEPA requirements and other laws, regulations, and policies.³³ The NPS permits research activities under 36 CFR 1.6, which prohibits the issuance of permits for activities that would adversely affect environmental values (among other criteria). The NPS permits research specimen collection under 36 CFR 2.5, which also prohibits collections that would damage park resources.

Under Alternative B (Implement Benefits-Sharing), mitigation measures would be applied to protect NPS research permit coordinators from being inappropriately influenced by benefits-sharing considerations. These measures would ensure that parks adhere to the strict standards in place regarding the issuance of NPS research permits. Mitigation efforts would focus on management controls as a means of managing the risk that benefits sharing might inappropriately influence park permitting decisions (*see* Chapter 4, Section 4.4.5.5).³⁴

Objective 3.2: Ensure that implementation of the alternatives does not discourage the conduct of research involving units of the NPS.

Development of the NPS benefits-sharing proposal was informed by the management practices of existing and potential benefits-sharing arrangements of other agencies and other countries around the world as well as the experience gained during development of the Yellowstone–Diversa CRADA (*see* Appendix G: Background for Benefits-Sharing and Technology Transfer). Insights gained suggested that benefits-sharing management practices that provide for the efficient and equitable sharing of valuable research results generated by research involving NPS research specimens would be most likely to be accepted by researchers without discouraging them from applying for NPS research permits. This concept was incorporated into Alternative B (Implement Benefits-Sharing).

The extent to which Alternative C (Prohibit Specimen Collection for Any Commercially-Related Research Purposes) could discourage research involving units of the NPS is evaluated in Chapter 4, Section 4.5.4.

Objective 3

Ensure that the NPS research permitting process is independent, objective, and unaffected by actions proposed in this DEIS.

Objective 3.1: Research involving units of the NPS continues to be permitted in accordance with all laws and is unaffected by alternatives proposed in this DEIS.

Objective 3.2: Ensure that implementation of the alternatives does not discourage the conduct of research involving units of the NPS.

1.5 Benefits-Sharing by National Parks and Other Organizations

Although this DEIS has been prepared due to the precedent-setting nature of implementing benefits-sharing in the NPS, benefits-sharing has already been implemented by various other organizations in the U.S. and around the world. For purposes of this DEIS, the term “benefits-sharing” refers to the equitable and efficient sharing of benefits—between researchers, their institutions, and a land management agency—that result from research involving research specimens originating from the lands under that agency’s jurisdiction.

Appendix G provides an overview of existing benefits-sharing arrangements. Depending on the facts and circumstances, the research results subject to a benefits-sharing agreement may generate either monetary or non-monetary benefits (or both). Existing benefits-sharing arrangements were examined by the NPS in preparation for proposing implementation of benefits-sharing.

1.6 Commercial Use of Research Results Discovered by Federal or Academic Scientists

In general, federal and academic institutions do not themselves commercialize research results. Usually, intermediate research results, as the intellectual property of the researcher and his institution, are offered for sale, lease, license, or other transfer for value to another institution for further research and development and eventual commercialization. The term “technology transfer” is used when such intellectual property is sold, leased, licensed, or otherwise transferred for value. Technology transfer by federal and academic research institutions is reviewed in Appendix G.

1.7 Legal Framework

The following sections provide a brief overview of relevant laws (Sections 1.7.1 *and* 1.7.2), regulations (Section 1.7.3), policies (Sections 1.7.4 *and* 1.7.5), and judicial decisions (Section 1.7.6) applicable to this DEIS.

The management of the National Park System and its programs is guided by the U.S. Constitution, public laws (*see* this chapter, Sections 1.7.1 *and* 1.7.2), treaties, proclamations, executive orders (*see* this chapter, Section 1.7.2), regulations (*see* this chapter, Section 1.7.3), and directives of the secretary of the interior and the assistant secretary for fish, wildlife, and parks, as interpreted by the judiciary (*see* this chapter, Section 1.7.6). NPS policy must be consistent with these authorities, and with appropriate delegation of authority.

Servicewide policy is articulated by the director of the NPS. *NPS Management Policies* is the primary servicewide policy document of the NPS, and is the highest of three levels of guidance documents in the NPS Directives System (*see* this chapter, Section 1.7.4). Interim

updates or amendments may be accomplished through Director's Orders (the second level of the NPS Directives System), which also serve as a vehicle to clarify or supplement *NPS Management Policies* to meet the needs of NPS managers (*see* this chapter, Section 1.7.5). The most detailed and comprehensive guidance on implementing servicewide policy is usually in the form of handbooks or reference manuals issued by associate directors (the third level of the NPS Directives System) (*see* this chapter, Section 1.7.5).

1.7.1 NPS Mandates: Laws Enacted by Congress Specifically for the NPS

The most important statutory directive for the NPS is provided by the interrelated provisions of the NPS Organic Act of 1916 and the NPS General Authorities Act of 1970, including amendments to the latter law enacted in 1978.

National Park Service Organic Act of 1916 and the NPS General Authorities Act of 1970, including amendments enacted in 1978

The NPS Organic Act establishes the NPS in the Department of the Interior to “promote and regulate the use of the Federal areas known as national parks, monuments, and reservations hereinafter specified.”³⁵

The key management-related provision of the Organic Act is: “[The National Park Service] shall promote and regulate the use of the Federal areas known as national parks, monuments, and reservations hereinafter specified . . . by such means and measures as conform to the fundamental purpose of the said parks, monuments, and reservations, which purpose is to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations.”³⁶

Congress supplemented and clarified the provisions of the Organic Act through the General Authorities Act. The key part of that act, as amended, is: “Congress declares that the national park system, which began with establishment of Yellowstone National Park in 1872, has since grown to include superlative natural, historic, and recreation areas in every major region of the United States. . . . The authorization of activities shall be construed and the protection, management, and administration of these areas shall be conducted in light of the high public value and integrity of the National Park System and shall not be exercised in derogation of the values and purposes for which these various areas have been established, except as may have been or shall be directly and specifically provided by Congress.”³⁷

The National Parks Omnibus Management Act of 1998 (NPOMA)

NPOMA directs the NPS to support both “science for parks” and “parks for science” (*see* Chapter 3, Section 3.2). NPOMA specifically incorporates scientific study as a purpose of the National Park System “to encourage others to use the National Park System for study to the benefit of park management as well as broader scientific value, where such study is consistent with the Act of August 25, 1916 (commonly known as the National Park Service Organic Act; 16 USC 1 *et seq.*).”³⁸ NPOMA directs the secretary of the interior to “assure that management of units of the National Park System is enhanced by the availability and utilization of a broad program of the highest quality science and information.”³⁹ NPOMA permits the secretary

of the interior to solicit, receive, and consider requests from federal, non-federal, public, or private entities to use any unit of the National Park System for purposes of scientific study.⁴⁰ Finally, it specifically authorizes the NPS to “enter into negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements.”⁴¹

Individual NPS unit enabling legislation

Each unit of the National Park System is governed by its own enabling legislation, which provides specific legal authorities and direction for each park.⁴² Parks must review their park’s enabling legislation to determine if it contains explicit guidance that would prevail over servicewide policy.

1.7.2 Other Laws

National Environmental Policy Act of 1969 (NEPA)

NEPA promotes efforts to prevent or eliminate environmental damage by requiring a “detailed statement on the environmental impact[s]” of “major Federal actions affecting the quality of the human environment.”⁴³ This DEIS has been prepared as NEPA directs to analyze the potential environmental impacts of benefits-sharing as well as alternatives to benefits-sharing. The DEIS also serves as a vehicle for the NPS to make a diligent effort to involve the interested and affected public before making decisions regarding benefits-sharing.

Federal Technology Transfer Act of 1986 (FTTA)

The FTTA stipulates that technology and industrial innovation are important to the U.S., and that “[c]ooperation among academia, Federal laboratories, labor, and industry” should be renewed, expanded, and strengthened for the purpose of improving the economic, environmental, and social well-being of the U.S.⁴⁴

The FTTA defines Cooperative Research and Development Agreements (CRADAs) as “any agreement between one or more Federal laboratories and one or more non-Federal parties under which the government, through its laboratories, provides personnel, services, facilities, equipment or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the mission of the laboratory.”⁴⁵

For purposes of the FTTA, a federal “laboratory” is defined as “a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government.”⁴⁶ The FTTA authorizes the directors of federal laboratories to enter into CRADAs with other federal agencies, state and local governments, industrial organizations, public foundations, private foundations, non-profit organizations, and other persons.⁴⁷ Like other federal facilities that carry out research activities, units of the National Park System that satisfy the FTTA definition of a “laboratory” are eligible to enter into CRADAs.⁴⁸

Executive Order 12591 authorizes delegation of authority to federal laboratories to enter into CRADAs with “other Federal laboratories, State and local governments, universities and the private sector.”⁴⁹ Alternative B (Implement Benefits-Sharing) proposes to implement this

authority by providing for individual parks that are laboratories under the FTTA to negotiate and implement benefits-sharing agreements.

1.7.3 NPS Regulations

Specific NPS regulations that have guided the preparation of this DEIS are reviewed briefly below. These regulations provide for the proper use, management, government, and protection of persons, property, and natural and cultural resources within areas under the jurisdiction of the National Park Service. These regulations implement the statutory purposes of units of the National Park System as established in the NPS Organic Act (see above).

Permits (36 CFR 1.6)

This regulation authorizes park superintendents to issue permits for activities that are otherwise restricted or denied to the general public and requires superintendents to “include in a permit the terms and conditions that the superintendent deems necessary to protect park resources.” Issuance of a permit is based on a determination by the park superintendent that the following factors “will not be adversely impacted”:

- Public health and safety
- Environment or scenic values
- Natural or cultural resources
- Scientific research
- Implementation of management responsibilities
- Proper allocation and use of facilities
- Avoidance of conflict among visitor use activities

Research specimens (36 CFR 2.5)

This regulation authorizes park superintendents to issue research specimen collection permits if the collection is necessary to scientific or resource management goals and only if such collections would not damage park resources.

Preservation of natural, cultural and archeological resources (36 CFR 1.6)

This regulation prohibits the sale or commercial use of “natural products.” There is an important distinction between sale or commercial use of natural products collected from national parks and the discovery of intellectual knowledge from research results followed by the development of commercial applications from that intellectual knowledge (*see this chapter, Section 1.1, and Chapter 2, Section 2.4.5*).⁵⁰

1.7.4 NPS Management Policies

Specific NPS policies that have guided the preparation of this DEIS are reviewed briefly below.

Once laws are enacted, authority for interpreting and implementing them is delegated to

appropriate levels of government. In carrying out this function, the NPS, like other federal agencies, develops policy to interpret the ambiguities of the law and to fill in the details left unaddressed by Congress in statutes. Servicewide policy is articulated by the director of the NPS. Policy sets the framework and provides direction for all management decisions, including the decision informed by this DEIS: whether or not to implement benefits-sharing.

Chapter 1: The Foundation

Chapter 1 of *NPS Management Policies 2001* describes and interprets the provisions of the NPS Organic Act and the NPS General Authorities Act as they relate to the need to avoid impairment of park resources and values. The “impairment” prohibited by these statutes is described as “an impact, in the professional judgment of the responsible NPS manager, that would harm the integrity of the park resources and values, including the opportunities that would otherwise be present for the enjoyment of those resources and values.” *NPS Management Policies 2001* also explains that “[w]hether an impact meets this definition depends on the particular resources and values that would be affected; the severity, duration, and timing of the impact; the direct and indirect effects of the impact; and the cumulative effects of the impact in question and other impacts.”

Chapter 4: Natural Resource Management

Chapter 4 provides that the NPS “will preserve the natural resources, processes, systems, and values of units of the national park system in an unimpaired condition” pursuant to the NPS Organic Act, NPOMA, NEPA, and other laws. It clarifies NPS policies relating to studies and collections, independent studies, and collections associated with development of commercial products.⁵¹

Chapter 8: Use of the Parks

Chapter 8 provides that “[s]tudies, research, and collection activities by non-NPS personnel involving natural and cultural resources will be encouraged and facilitated when they otherwise comport with NPS policies,” and that “[s]cientific activities that involve field work or specimen collection . . . require a permit issued by the superintendent that prescribes appropriate conditions for protecting park resources, visitors, and operations.”⁵²

1.7.5 NPS Director’s Orders, Handbooks, and Other Guidance Documents

Director’s Orders clarify or supplement the NPS Management Policies to meet the needs of NPS managers. Subordinate to Director’s Orders, handbooks or reference manuals issued by associate directors provide the most detailed and comprehensive guidance on implementing servicewide policy. Handbooks do not impose any new servicewide requirements unless the NPS director has specifically authorized them to do so, but often reiterate or compile requirements (i.e., laws, regulations, policies) that have been imposed by higher authorities. NPS managers find additional guidance in various other documents prepared under the NPS director’s authority.

Specific NPS guidance documents that were consulted in the preparation of this DEIS are reviewed briefly below.

Director's Order and Handbook 12: Conservation Planning, Environmental Impact Analysis, and Decision-Making

This handbook provides instructions for the NEPA process in the NPS. The sections of this handbook derive in whole or in part from Council on Environmental Quality (CEQ) regulations or Department of the Interior NEPA guidelines, giving them the force of law. The processes described in this handbook are binding on all NPS personnel.

This handbook also directs that NPS management decisions be based on “ample technical and scientific studies properly considered and appropriate to decisions made.”⁵³ It prohibits the NPS from undertaking any activity that “would, or is likely to, impair park resources or values.”⁵⁴

Director's Order 20: Agreements

Director's Order 20 encourages NPS park and program managers to “actively seek opportunities to efficiently and economically accomplish the NPS mission by entering into advantageous relationships with Federal and non-Federal entities.”

Administrative Guide for Park Research Coordinators

This guide describes the procedures a park is to use for determining whether or not to issue an NPS Scientific Research and Collecting Permit (research permit). It explains that an application for a research permit should be evaluated for its scientific validity, researcher and institutional qualifications, its benefit to the park service and the public, and its actual or potential impacts to park resources, visitor experiences, wilderness, or safety. The guide notes that the NPS should encourage “a broad range of research in parks.”

NPS Scientific Research and Collecting Permits: General Conditions

The general conditions provide that permittees shall comply with all applicable laws and regulations of the National Park System and other federal, state, and area laws, and that “[n]o specimens (including materials) may be collected unless authorized on the Scientific Research and Collecting Permit.”⁵⁵ They prohibit unauthorized third-party transfers of any specimens collected. They stipulate that research results derived from collected specimens must be used for scientific and educational purposes only, and that research results may not be used commercially unless the permittee has entered into a CRADA or other approved benefits-sharing agreement with the NPS.⁵⁶

Two of the alternatives considered in this DEIS would require further clarification of these conditions through preparation of new Director's Orders. Alternative A would allow the use of research results for commercial purposes without a benefits-sharing requirement (*see* Chapter 2, Section 2.3). Alternative C would not authorize the commercial use of research results (with some exceptions) and would not require benefits-sharing (*see* Chapter 2, Section 2.5). Alternative B would implement the general conditions as written (*see* Chapter 2, Section 2.4).

NPS Natural Resource Challenge

The NPS Natural Resource Challenge states, “[n]ational parks are preserved so that this generation and future generations can enjoy, benefit, and learn from them.”⁵⁷ It notes

that the NPS requires more information about plants, animals, ecosystems, and their interrelationships in order to protect them, and must enlist others in the scientific community to help.⁵⁸ It states, “Acquiring, applying, and promulgating scientific knowledge gained in parks to ensure protection and enjoyment requires cooperation with public agencies, universities, and non-governmental organizations;” “[P]arks can and should be centers for broad scientific research and inquiry;” and “Research should be facilitated in parks where it can be done without impairing other park values.”⁵⁹

National Park Service Strategic Plan FY2001–2005

The NPS Strategic Plan states that the mission of the NPS is to preserve resources and serve the public, and explains that the NPS “preserves unimpaired the natural and cultural resources and values of the national park system for the enjoyment, education, and inspiration of this and future generations.”⁶⁰ It notes that the NPS cooperates with partners to extend the benefits of natural and cultural resource conservation and outdoor recreation throughout this country and the world.⁶¹ It establishes that the NPS’s guiding principles include “[a]pplying scientific information to park management decisions to preserve park resources” and “[p]romoting parks as centers for broad scientific and scholarly inquiry to benefit society.”⁶²

1.7.6 Judicial Decisions

Edmonds Institute, et al. v. Babbitt, et al., 93 F. Supp. 2d 63 (DDC 2000)

The U.S. District Court heard plaintiffs’ claims that the Yellowstone–Diversa CRADA violated the National Park Service (NPS) Organic Act of 1916, the Yellowstone National Park Organic Act, and the FTTA, and then rejected those claims on all counts and dismissed the plaintiffs’ case with prejudice. Specifically, the court ruled that the Yellowstone–Diversa CRADA satisfies the requirements of the NPS and Yellowstone National Park Organic Acts as well as the FTTA,⁶³ does not authorize an impermissible “consumptive use” of park resources,⁶⁴ does not conflict with the conservation mandate of the NPS and Yellowstone Organic Acts,⁶⁵ and does not involve the “sale or commercial use” of park resources.⁶⁶

Edmonds Institute, et al. v. Babbitt, et al., 42 F. Supp. 2d 1 (DDC 1999)

The U.S. District Court heard plaintiffs’ claims that the Yellowstone–Diversa CRADA violated the public trust doctrine and that the NPS failed to demonstrate compliance with NEPA, dismissed the claim regarding the public trust doctrine, and ruled that the NPS had failed to demonstrate compliance with NEPA, and suspended the CRADA pending compliance with the court’s order that the NPS meet the requirements mandated by NEPA.⁶⁷

Public Citizen Health Research Group v. National Institutes of Health, et al., CA No. 00-1847 (DDC 2002) (Memorandum Opinion dated March 11, 2002)

The U.S. District Court ruled that financial information relating to royalty payments arising under certain licensing agreements and CRADAs are exempt from disclosure under the federal Freedom of Information Act.

Diamond v. Chakrabarty, 447 US 303 (1980)

The U.S. Supreme Court ruled that a live, human-modified microorganism is patentable subject matter under 35 USC 101.

JEM Ag Supply dba Farm Advantage v. Pioneer Hi-Bred Int'l, 534 US 124 (2001)

The U.S. Supreme Court ruled that plant varieties are eligible for protection by utility patents issued pursuant to 35 USC 101, as well as under the Plant Patent Act of 1930 (35 USC 161 *et seq.*), and the Plant Variety Protection Act of 1970 (7 USC 2321 *et seq.*).

1.8 Summary of Public Involvement/Scoping

Scoping is an early and open process for determining the scope of environmental issues and alternatives to be addressed in an EIS. The public plays an integral role in the scoping process. The NPS used the various points of view expressed in scoping comments submitted for this EIS to frame the issues to be resolved through the NEPA process and documented in this DEIS.

Scoping for this DEIS occurred June–August 2001 and April–May 2002. During the scoping period, two newsletters were mailed to more than 5,000 people, requesting comments.⁶⁸ A web site provided background information and invited people to comment via e-mail. A press release and fact sheet were distributed to national news media. Articles appeared in a variety of newspapers. Notices were posted in the nationwide NPS Morning Report.

In total, 118 comment messages were received on a variety of items. Most of the messages were received from individuals. Twenty-five organizations also submitted comments. Typically, a single message contained multiple, topical comments. The NPS identified 294 separate topical comments within these 118 messages (*see also* Appendix D: Public Involvement—Scoping).

Every comment in every message received during scoping was identified for consideration by the Interdisciplinary Team (IDT), including comments that were outside the scope of this DEIS. All comments and concerns were considered, whether they were presented by several people or a single person. Emphasis in this process was on the content of the comment, rather than the number of people who submitted it.

Initially the NPS planned to write an Environmental Assessment (EA) for benefits-sharing. However, scoping comments persuaded the NPS that an EIS would be more appropriate. Issues framed by scoping are described below in Section 1.12 of this chapter.

Perhaps because information available to the public about the scoping process was presented in a short newsletter that necessarily gave only a brief outline of benefits-sharing, the NPS received several kinds of comments that did not relate to this DEIS. For example, some people assumed that without benefits-sharing, scientific research would not occur in NPS units, and they suggested that scientific research projects should be subject to NEPA review, not realizing that every research permit decision is already required to undergo a case-specific NEPA review. In addition, some people assumed incorrectly that this DEIS might propose wholesale commercialization of park resources. These concerns have been answered in this DEIS by the specific details included in the Alternatives as described in Chapter 2.

1.9 Issues and Impact Topics from Scoping

During scoping, the public and the NPS Interdisciplinary Team (IDT) identified and consolidated a variety of concerns about implementation of benefits-sharing. Some of the concerns raised during scoping are analyzed as impact topics in Chapter 4 (*see* this chapter, Section 1.9.1). Other concerns, such as general approval or disapproval of benefits-sharing, were addressed by incorporating the concern into one or more alternatives (*see* Chapter 2, Section 2.6). Issues, impacts, and concerns that were not within the scope of the decision to be made in the Final EIS, or will not be significantly impacted by any of the alternatives, were not analyzed further (*see* this chapter, Section 1.9.2).

1.9.1 Issues Analyzed as Impact Topics in Chapter 4

Potential impacts of the alternatives on each of the following issues were analyzed under each of the alternatives.

- (1) NPS Natural Resource Management (*see* Chapter 3, Section 3.2);
- (2) NPS Visitor Experience and Enjoyment (*see* Chapter 3, Section 3.3);
- (3a) Social Resources: The Research Community (*see* Chapter 3, Section 3.4); and
- (3b) Social Resources: NPS Administrative Operations (*see* Chapter 3, Section 3.5.)

(1) NPS Natural Resource Management

Scoping respondents advised the NPS to ensure that the information discovered during park research would be available to park managers. Comments were received supporting scientific endeavors in parks, and warning against any action that might chill research activities that could improve understanding of park resources.

Under the proposal, Alternative B (Implement Benefits-Sharing), knowledge, training and education, special services, research-related equipment, and monetary benefits generated by a benefits-sharing agreement would be used by natural resource managers to assist with meeting natural resource management goals. Alternative B is therefore predicted to primarily have beneficial impacts on NPS natural resource management. Chapter 3, Section 3.2 describes natural resource management in the NPS. The potential impacts of benefits-sharing on NPS natural resource management are analyzed in Chapter 4 for each alternative.

(2) NPS Visitor Experience and Enjoyment

The proposal, Alternative B (Implement Benefits-Sharing), is predicted to have primarily beneficial impacts on visitors in two ways: by affecting natural resource management, and by affecting interpretive services. Knowledge, training and education, special services, or research-related equipment generated by a benefits-sharing agreement could be used to prepare or conduct interpretive services. Chapter 3, Section 3.3 describes the aspects of visitor experience and enjoyment in the NPS that could be affected by the alternatives. The potential impacts on visitor experience and enjoyment are analyzed in Chapter 4 for each alternative.

(3a) Social Resources: The Research Community

The proposal, Alternative B (Implement Benefits-Sharing), is predicted to have a variety of impacts on researchers who hold NPS research permits, such as potential economic gains for researchers, or new requirements placed on research activities or use of research results. In addition, potential impacts of the alternatives on the quantity of independent research activities in parks were analyzed. Chapter 3, Section 3.4 describes the researchers who could be affected by the alternatives. These potential impacts are analyzed in Chapter 4 for each alternative.

(3b) Social Resources: NPS Administrative Operations

The proposal, Alternative B (Implement Benefits-Sharing), is predicted to have a variety of impacts on NPS administrative operations related to the administrative burden associated with each alternative. Chapter 3, Section 3.5 describes the NPS administrative operations that could be affected by the alternatives, the parks that are most likely to be affected, and the administrative resources available to parks. The predicted impacts on relevant NPS administrative operations are presented in Chapter 4 for each alternative.

1.9.3 Issues Not Evaluated Further in this DEIS

Issues and concerns that are not within the scope of the decision to be made in the Final EIS or that would experience impacts from the alternatives that are minor or less were not analyzed further. Issues not analyzed in detail, and the reasons why they were not subject to detailed analysis in the DEIS, are explained in the following sections. Potential impacts on the following topics were not evaluated in the DEIS.

1.9.3.1. Issues identified during scoping

Genetic engineering

The proposal, Alternative B (Implement Benefits-Sharing), would have no impact on genetic engineering. Issues relating to genetic engineering and the safety of any new medicines, agricultural products, or other discoveries that could result from research involving NPS research specimens are regulated by other agencies, such as the Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture.

Intellectual property rights

The proposal, Alternative B (Implement Benefits-Sharing), would have no impact on intellectual property rights as recognized in U.S. intellectual property rights laws. No federal action within the scope of this DEIS is proposed to modify any existing U.S. intellectual property rights laws.⁶⁹

Congressional appropriations

Overall NPS funding is beyond the scope of the analysis of the potential environmental impacts of benefits-sharing. Existing NPS authority to negotiate equitable, efficient benefits-sharing arrangements with the research community is a congressional authorization, not an appropriation.

Administration of scientific research activities in the NPS

Authorization to conduct scientific research in national parks is subject both to well-established NPS regulations and to separate NEPA compliance procedures (*see* this chapter, Section 1.6). Federal actions analyzed in this DEIS would not change the compliance procedures under which research activities could be conducted.

1.9.3.2 Other legal compliance disclosures

CEQ regulations (40 CFR Part 1500) and NPS policy (NPS DO-12) require that the following mandatory topics be addressed in every EIS. The discussion below addresses the topics either by providing the rationale for dismissing the topic from further consideration or directing the reader to the appropriate section of the document where further information on the topic is provided.

Possible conflicts between the proposed action and local, state, or tribal plans, policies, or controls

Scoping and public involvement processes conducted for this DEIS have not revealed potential conflicts with plans, policies, or controls of local, state, or tribal governments. In addition, the actions proposed in this document do not recommend any changes to existing local, state, or tribal plans, policies, or controls. Protection of the intellectual property rights of tribes is discussed in Chapter 2, Alternative B, Section 2.4.1. In some instances, the NPS has regulatory or managerial authorities and responsibilities for lands that are under joint jurisdiction or are not federally owned. These authorities and responsibilities may include the issuance of NPS research permits. Ownership of research specimens collected from these areas may vary according to jurisdiction and land status.

Energy requirements and conservation potential

No alternative in this document will affect or propose a change in energy use in NPS areas. Therefore, this topic was dismissed from further consideration.

Natural or depletable resource requirements and conservation potential

The range of alternatives, and the purpose and need in this document, are fully within the scope of NPS mandates and policies concerning these topics. Bioharvesting (the extraction of natural resources for commercial use) would continue to be prohibited.⁷⁰ Specimen collection would continue to be limited and managed through existing regulation and policy (*see* this chapter, Section 1.2.3), with the exception that Alternative C would provide an additional restriction prohibiting the collection of research specimens for research that was identified or acknowledged by the researcher as being associated with the potential for commercial development. Specimen collection is reviewed and authorized under a process separate and distinct from the benefits-sharing arrangements proposed in this document. As such, a general review of specimen collection activities is outside the scope of this document. While specimen collection is discussed under each alternative, its effects do not vary substantially by alternative, and no changes to the specimen collection regulations or policies are proposed (except in Alternative C as noted above). Therefore, this topic was dismissed from further consideration.

Environmental justice

Executive Order 12898, “General Actions to Address Environmental Justice in Minority Populations and Low Income Populations,” requires all federal agencies to incorporate environmental justice into their missions by identifying and addressing disproportionately high and adverse human health or environmental effects of their programs and policies on minorities and low-income populations and communities. No element of the alternatives would have health or environmental effects on minorities or low-income populations or communities as defined in the Environmental Protection Agency’s Environmental Justice Guidance. Therefore, environmental justice within the meaning of Executive Order 12898 was not considered as an impact topic in this document.

Wetlands

Executive Order 11990 (Protection of Wetlands) requires federal agencies such as the NPS to evaluate the impacts its actions are likely to have on wetlands. The executive order requires that short- and long-term adverse impacts associated with occupancy, modification, or destruction of wetlands be avoided whenever possible. No activities are proposed that would alter or modify wetlands. Therefore, wetlands were not considered as an impact topic in this document.

Migratory birds

Executive Order 11386 (Protection of Migratory Birds) requires federal agencies such as the NPS to ensure that environmental analyses of federal actions required by the NEPA evaluate the effects of actions and agency plans on migratory birds, with emphasis on species of concern. No activities are proposed that would involve migratory birds or alter their habitats. Therefore, migratory birds were not considered as an impact topic in this document.

Floodplain management

Executive Order 11988 and NPS policy require that impacts to floodplains be considered in NPS undertakings. No proposed activities would occur within or encroach upon floodplains. Therefore, floodplains were not considered as an impact topic in this document.

Prime and unique farmlands

In August 1980, the CEQ directed that federal agencies must assess the effect of their actions on farmland soils classified by the U.S. Department of Agriculture’s Natural Resources Conservation Service as prime or unique. Prime or unique farmland is defined as soil that particularly produces general crops such as common foods, forage, fiber, and oil seed, or unique farmland that produces specialty crops such as fruits, vegetables, and nuts. No soils would be disturbed under this proposal. Therefore, the topic of prime and unique farmlands was not considered as an impact topic in this document.

Threatened and endangered species

No negative effects on threatened or endangered species have been identified in relation to the actions proposed in this document, and the NPS does not anticipate negative effects on these species. Threatened and endangered species may experience an indirect long-term benefit under some proposed actions, because increased knowledge would allow for better management of these species and their habitat. If benefits-sharing is implemented by the

NPS, resulting projects would receive a separate environmental review for potential project-specific impacts to threatened and endangered species and their habitat. This is the case for any project proposed by a park, regardless of its source. Consultation with the U.S. Fish and Wildlife Service (USFWS) concerning threatened and endangered species under 50 CFR part 402, which implements the Endangered Species Act of 1973, will be completed. As part of the consultation process, the NPS is seeking the review and concurrence of the USFWS with its determination of effect on threatened and endangered species.

Archeological and cultural resources, including historic properties listed or eligible for the National Register of Historic Places

For the most part, cultural, architectural, and historic resources are considered to be outside the scope of analysis, because the alternatives discuss benefits-sharing arrangements in relation to biotic or natural resources. If benefits-sharing is implemented by the NPS, resultant projects would receive a separate environmental review for potential project-specific impacts. No effects on listed eligible National Register properties or other cultural resources have been identified in relation to the actions proposed in this document, and the NPS does not anticipate effects on these resources. Compliance with the National Historic Preservation Act, as amended, will occur through consultation with National Conference of State Historic Preservation Officers (NCSHPO). Specifically, the identification and evaluation of potential effects on cultural resources will be conducted with NPS staff, American Indian tribes, and NCSHPO. The NPS is seeking review and concurrence of this determination from NCSHPO.

Ecologically critical areas, wild and scenic rivers, or other unique natural resources
The range of alternatives, and the purpose and need expressed in this document, are fully within the scope of NPS mandates and policies concerning these topics. No action proposed in the alternatives would affect the eligibility or designation of a wild and scenic river or wilderness area. If benefits-sharing is implemented by the NPS, resultant projects would receive a separate environmental review for potential project-specific impacts to wilderness, wild and scenic rivers, or other ecologically critical or unique natural resources. This is the case for any project proposed by a park, regardless of the source of the project.

Public health and safety

Public health and safety would not be impacted directly by any of the alternatives. There could be indirect beneficial effects on public health, for example, resulting from increased collaboration between park staff and researchers leading to the development of new pharmaceuticals (*see* this chapter, Section 1.2.4). However, because of the uncertainties that characterize the scientific research and development process that are described throughout this DEIS, it would be speculative to attempt to describe any specific impact on public health that could result.

Sacred sites and Indian Trust resources

Native American tribes who may be affected by the alternatives will be contacted for their input and comment on this document. No effects on sacred sites or Indian Trust resources have been identified in relation to actions proposed in this document, and the NPS does not anticipate effects on these resources. Should benefits-sharing agreements be employed by the NPS, resultant projects would receive a separate environmental review for potential project-

specific impacts. Potential unforeseen, park-specific issues that may arise in the future would be resolved on a case-by-case basis.

Notes

Section 1.1 Introduction

¹ This DEIS uses the term “national parks” to include any unit of the National Park System.

² 36 CFR 2.1.

Section 1.2 Background

³ See 48 Fed. Reg. 30252, 30274 (June 30, 1983).

⁴ As part of the research permit terms, scientists are required to submit a yearly summary of their park research activities, known as an Investigator’s Annual Report. In addition, copies of field notes and scientific publications may be required by the park.

⁵ See, e.g., B. Marrs and M. Madigan, “Extremophiles,” *Scientific American* (April 1997): 82–87.

⁶ Diversa remained subject to all of the restrictions designed to protect NPS resources contained in its pre-existing Scientific Research and Collecting Permits and other underlying NPS regulations. See also *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63, at 65–66 (DDC 2000) (“Prior to the CRADA, Diversa or other researchers were free to remove any specimen within the purview of their permit and develop it as they wished. If such development led to commercial uses, the Park Service never saw any proceeds from the derivative products. Thus, recognizing that resources yielding potentially valuable properties were being removed from Yellowstone with no remuneration to Yellowstone or the American people, officials at Interior began to consider a resource management scheme, patterned on the successes of Costa Rica and other nations, which would use bioprospecting to provide funds and incentives for the conservation of biological diversity.”).

⁷ These units are variously designated as national parks, monuments, preserves, lakeshores, seashores, wild and scenic rivers, trails, historic sites, military parks, battlefields, historical parks, recreation areas, memorials, and parkways (National Park Service, “Statistical Abstract,” (2001), available online at <www2.nature.nps.gov/stats/abst2001.pdf>, last accessed February 1, 2006).

⁸ National Park Service, *NPS Management Policies 2001*, 1.4.3. (Washington, D.C.: U.S. Department of the Interior, 2000), hereafter *NPS Management Policies 2001*.

⁹ More detailed descriptions of NPS natural resources, including plants, fish, wildlife and their habitats, have been developed by individual park units (see <www.nature.nps.gov>, last accessed February 1, 2006).

¹⁰ R. G. Bailey, *Descriptions of the Ecoregions of the United States*, 2d ed. (1st ed. 1980) (Washington, D.C.: USDA Forest Service, 1995).

¹¹ National Park Service, “Application Procedures and Requirements for Scientific Research and Collecting Permits (2002), available online at <<http://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed February 1, 2006.

¹² 36 CFR 1.6(e).

¹³ See, e.g., National Research Council, *Science and the National Parks* (Washington, D.C.: National Academy Press, 1992) and R. W. Sellars, *Preserving Nature in the National Parks: A History* (New Haven: Yale University Press, 1997).

¹⁴ See also National Parks Omnibus Management Act of 1998, at Section 205(a) (16 USC 3935(a)): “The Secretary may solicit, receive, and consider requests from Federal or non-Federal public or private agencies, organizations, individuals, or other entities for the use of any unit of the National Park System for purposes of scientific study.”

¹⁵ 36 CFR 2.5. See also this document, “Chapter 3, Section 3.5.3 Park units most likely to be affected by Alternative B (Implement Benefits-Sharing).”

¹⁶ National Park Service Research Permit Reporting System (RPRS) data, available online at <<http://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed February 1, 2006.

¹⁷ The number of research projects ongoing throughout the NPS between 1992 and 2004 was estimated by reviewing servicewide research reports compiled in the RPRS (see <<http://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed February 1, 2006).

¹⁸ W. Schumacher, NPS Bibliographic Coordinator, pers. comm. to Benefits-Sharing Evaluation Team, August 16, 2005.

¹⁹ *Billings Gazette*, “Microbes Have Variety of Uses” (December 5, 1993).

²⁰ *Genetic Engineering News* (March 15, 1994): 35.

²¹ *San Jose Mercury News* (July 25, 1994): 8F.

²² *Discover*, “Rubber Reborn” (July 1996): 88.

²³ T. M. Burton, “Yellowstone’s Geysers Spout Valuable Microorganisms,” *Wall Street Journal* (August 11, 1997): B1.

²⁴ Testimony of D. Allan Bromley, Director, Office of Science and Technology Policy, before the Committee on Science, Space, and Technology, U.S. House of Representatives, February 20, 1991. It should be noted that Dr. Brock was affiliated with Indiana University (not Wisconsin) when *T. aquaticus* was first discovered in 1966. See T. Brock, “The Value of Basic Research: Discovery of *Thermus aquaticus* and Other Extreme Thermophiles,” *Genetics* 146: 1207; see also F. Grifo and J. Rosenthal, *Biodiversity and Human Health* (Washington, D.C.: Island Press, 1997), xiii, “The contributions of biodiversity to human health have even more potential today when the sciences are able to make extraordinary contributions at the level of the molecule. . . . Probably no more dramatic example exists than the polymerase chain reaction: an extraordinary magnifying reaction that can multiply tiny amounts of genetic material a billion times over in a very short time. This Nobel Prize winning reaction depends on a heat resistant enzyme from a bacterium isolated from a Yellowstone hot spring. Valuable in a wide array of research, PCR is the fundamental underpinning of the human genome project which will characterize our entire genetic composition and render benefits for human health beyond estimation.”

Section 1.3 Need for a proposal to implement benefits-sharing (specific problems with existing procedures)

²⁵ General Condition 6 of the standardized NPS Scientific Research and Collecting Permit reads, in part, “Any specimens collected under this permit, any components of any specimens (including but not limited to natural organisms, enzymes or other bioactive molecules, genetic materials, or seeds), and research results derived from collected specimens are to be used for scientific or educational purposes only, and may not be used for commercial or other revenue-generating purposes unless the permittee has entered into a Cooperative Research And Development Agreement (CRADA) or other approved benefit-sharing agreement with the NPS” (National Park Service, “General Conditions for Scientific Research and Collecting Permit,” Section 6, available online at <<http://science.nature.nps.gov/research/ac/ResearchIndex>>, last accessed February 1, 2006).

²⁶ The courts also have upheld the distinction recognized by the NPS between management of “research specimens” and “research results.” See *Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000).

²⁷ See National Park Service, “General Conditions for Scientific Research and Collecting Permit,” Section 6, which reads, in part: “Collected specimens that are not consumed in analysis or discarded after scientific analysis remain federal property. The NPS reserves the right to designate the repositories of all specimens removed from the park and to approve or restrict reassignment of specimens from one repository to another. Because specimens are Federal property, they shall not be destroyed or discarded without prior NPS authorization. . . . The sale of collected research specimens or other unauthorized transfers to third parties is prohibited.”

²⁸ National Park Service, *The Natural Resource Challenge: The National Park Service’s Action Plan for Preserving Natural Resources* (Washington, D.C.: National Park Service, 1999).

²⁹ *NPS Management Policies 2001*, Chapter 7.

Section 1.4 Objectives of the Proposal and Its Alternatives (the Purpose of the EIS)

³⁰ National Parks Omnibus Management Act of 1998, Section 5932.

³¹ See, e.g., National Research Council, *Science and the National Parks*, and Sellars, *Preserving Nature in the National Parks*.

³² *NPS Management Policies 2001*, 4.2.

³³ National Park Service, “Application Procedures and Requirements for Scientific Research and Collecting Permits.”

³⁴ The U.S. Office of Management and Budget (OMB) instructs all federal agencies regarding methods to ensure that federal programs are managed with integrity and in compliance with applicable law (see OMB Circular No. A-123.) *NPS Management Policies 2001* requires the NPS to comply with these instructions (see *NPS Management Policies 2001*, 1.8.1). This DEIS follows OMB direction to ensure that those who approve park research permits are not influenced by benefits-sharing considerations.

Section 1.7 Legal framework

³⁵ 16 USC 1.

³⁶ *Ibid.*

³⁷ 16 USC 1a-1.

³⁸ 16 USC 5931.

³⁹ 16 USC 5932.

⁴⁰ 16 USC 5935(a).

⁴¹ 16 USC 5935(d).

⁴² *See* 16 USC 21 *et seq.*

⁴³ 42 USC 4331–4332.

⁴⁴ 15 USC 3701(1), (3).

⁴⁵ 15 USC 3710a(d)(1).

⁴⁶ 15 USC 3710a(d)(2)(A).

⁴⁷ 15 USC 3710a(a), (a)(1).

⁴⁸ *See Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000).

⁴⁹ 52 Fed. Reg. 13414 (April 22, 1987).

⁵⁰ *See Edmonds Institute, et al. v. Babbitt, et al.*, 93 F. Supp. 2d 63 (DDC 2000).

⁵¹ *NPS Management Policies 2001*, “Chapter 4: Natural resource management, Section 4.2 Studies and collections”; “Section 4.2.2 Independent studies”; and “Section 4.2.4 Collection associated with the development of commercial products.”

⁵² *Ibid.*, “Chapter 8: Use of the parks, Section 8.10 Natural and cultural studies research and collection activities.”

⁵³ National Park Service. 2001. *Director’s Order 12: Conservation planning, environmental impact analysis, and decision-making*, Section 4.4.

⁵⁴ *Ibid.*, Section 4.7.

⁵⁵ *See* National Park Service, “General Conditions for Scientific Research and Collecting Permit,” Section 6.

⁵⁶ *See ibid.*

⁵⁷ *NPS Natural Resource Challenge*, “Section 1, Goals.”

⁵⁸ *Ibid.*, “Introduction.”

⁵⁹ *Ibid.*, “Challenges and strategies: collaboration”; and “Challenges and strategies: parks for science.”

⁶⁰ National Park Service, “Introduction” and “Mission statement,” *National Park Service Strategic Plan FY2001–2005* (United States Department of the Interior, NPS D-1383/August 2000).

⁶¹ *Ibid.*

⁶² *Ibid.*, “Introduction, Guiding Principles: Science and Research.”

⁶³ 93 F. Supp. 2d 63, at 67–71.

⁶⁴ 93 F. Supp. 2d 63, at 70.

⁶⁵ *Ibid.*

⁶⁶ 93 F. Supp. 2d 63, at 71–72.

⁶⁷ 42 F. Supp. 2d 1, at 16–17 and 20.

Section 1.8 Summary of public involvement/scoping

⁶⁸ The mailing list of more than 5,000 included research scientists working in national park units servicewide, biotechnology associations, Native American tribes, organizations with an interest in national parks, NPS personnel, and others who expressed interest.

⁶⁹ The U.S. Supreme Court has ruled on the applicability of various U.S. intellectual property rights laws in connection with inventions arising from the use of biological specimens. *See, e.g., Diamond v. Chakrabarty*, 447 US 303 (1980); and *JEM Ag Supply Inc. dba Farm Advantage Inc. v. Pioneer Hi-Bred International, Inc.*, 534 US 124 (2001).

⁷⁰ In some cases, natural resource extraction activities are specifically mandated by a park’s enabling legislation. Such mandated uses of park resources would not be affected by the alternatives in this DEIS.

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